DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 10, 2015

Medicrea International
Ms. Audrey Vion
Regulatory Affairs Manager
14 Porte du Grand Lyon
01700 Neyron
FRANCE

Re: K150049
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP, MNI, OSH
Dated: January 8, 2015
Received: January 12, 2015

Dear Ms. Vion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150049

Device Name
PASS LP Spinal System

Indications for Use *(Describe)*
The PASS LP Spinal Systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures
- Dislocation
- Failed previous fusion (Pseudarthrosis)
- Spinal Stenosis
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

The PASS LP Spinal Systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The PASS LP also include hooks and rods and sacral/iliac screws indicated for degenerative disc disease (DDD) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, Pseudarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

VI. 510(K) SUMMARY

1. DEVICE SUBMITTER

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Date Prepared: 08/01/2014

2. DEVICE

Name of Device: PASS LP Spinal System

Common or Usual Name: Spinal Fixation Appliances
Orthosis, spinal pedicle fixation
Orthosis, spondylolisthesis spinal fixation
Appliance, fixation, spinal interlaminal
Pedicle screw spinal system, Adolescent Idiopathic Scoliosis

Classification Name: Pedicle Screw Spinal System 888.3070 (Class II)
Spinal interlaminal fixation orthosis 888.3050 (Class II)

Regulatory Class: Orthosis, spinal pedicle fixation
Orthosis, spondylolisthesis spinal fixation
Appliance, fixation, spinal interlaminal
Pedicle screw spinal system, Adolescent Idiopathic Scoliosis

Product Code: MNI; MNH; KWP; OSH.

3. PREDICATE DEVICE

The primary predicate of this submission is

- PASS LP Patient Specific Rods(MEDICREA INTERNATIONAL, K140738)

An additional predicate for this submission is

- PASS LP Spinal System (MEDICREA INTERNATIONAL, K123138)

These predicates have not been subject to a design-related recall.
No reference device was used in this submission.

4. DEVICE DESCRIPTION

The UNiD Rods have to be used with the PASS LP Spinal System designed to contribute to correction and surgical stabilization of the thoracic, lumbar and sacral spine.
The Patient Specific Rod is a rod bent before the surgery by MEDICREA, following the profile defined by the surgeon only, specific to a unique patient.

The system consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink components. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 and ISO 5832-3 or cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

The purpose of this submission is to offer the existing cleared reference in sterile version.

A subset of PASS LP Spinal System components may be used for posterior pedicle screw fixation. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, sacral hooks, sacral plates, iliac screws, clamps, nuts and crosslink components. These components can be rigidly locked into a variety of configurations, with each construct being tailored made for the individual case.

Materials: Titanium alloy and Cobalt-chromium-molybdenum alloy

This Special 510(k) premarket notification is submitted for the additional offering of gamma sterilzed UNiD Rods.

5. INDICATIONS FOR USE

The PASS LP Spinal Systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures
- Dislocation
- Failed previous fusion (Pseudarthrosis)

- Spinal stenosis
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

The PASS LP Spinal Systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.